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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/674,277

02/13/2001

Dominique Therese Marie Frechon

P66034US0

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

02/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/674,277 | Applicant(s) FRECHON ET AL. | |
| | Examiner Patricia A. Duffy | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,21,24,25 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-30 is/are allowed.
- 6) ☒ Claim(s) 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 24 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11-29-2007</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-29-07 has been entered. The remarks and amendment filed 11-29-07 has been entered into the record. Claims 1-19, 22, 23, 26 and 31-60 have been cancelled. Claims 20, 21, 24, 25, 27, 28, 29 and 30 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 27-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for lack of deposit declaration is withdrawn in view of the deposit declaration provided.

The rejection of claims 22-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention applicants is withdrawn in view of the amendment to the claims.

The rejection of claim 20 stands rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brunder et al (Microbiology, 146:3305-3315, 1996) is withdrawn in view of the amendment to the claims.

The rejection of claims 20 and 25 under 35 U.S.C. 102(b) as being clearly anticipated by Makino et al , (DNA Research, 5(1):1-9, Feb 28, 1998) *in light of* GenEMBL Accession Number AB011549 is withdrawn in view of the amendment to the claims.

The rejection of claims 20-25 under 35 U.S.C. 103(a) as being unpatentable over Makino et al , (DNA Research, 5(1):1-9, Feb 28, 1998) in view of Schmidt et al, Microbiology 142(4):907-914, 1996 and Kennell et al 1971("Principles and properties of nucleic acid hybridization", Progr. Nucl. Acid Res. Mol. Biol. 11: 259-301) in light of GenEMBL Accession Number AB011549 is withdrawn based on Applicants amendments to the claims and that for claims 21 and claims dependent thereon, it is unexpected to find a particular sequence from a virulence plasmid that is uniquely characterizes it as serotype 0157:H7.

Rejections Maintained

Claims 20 and 21 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons made of record in the previous office actions and herein.

Applicants argue that the amendment places the claims in condition with the written description requirement. The amendments do not obviate this rejection. This is not persuasive because the courts have held that the specification must have a representative number of species to support a genus claim and that the written description of the specification must convey possession of the genus of derivatives. Applicants' have no written description for any of these other desirable compounds are not enabled for such and that applicants' are not entitled for dominance of further patentable inventions by claims that are insufficiently supported by the specification (*In re Fisher*, 166 USPQ 18, CCPA (1970)). The claims are drawn to a genus of nucleic acids wherein the genus is defined by hybridization conditions and therefore have an undefined structure in common. The scope of the claims encompass substantial variety of nucleic acids by derivation by substitution and deletion and hybridizing under conditions with no temperature. The disclosure fails to provide sufficient description as to structural and functional features of the genus, such as conserved regions that are critical to function

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and structure of the claimed genus. There is no description of the sites at which variability may be tolerated and there is no information with respect to structure and function of detection of enterohaemorrhagic *E. coli* microorganism, and 0157:H7 in particular as opposed to any other non-enterohaemorrhagic *E. coli* nucleic acid. It is noted that a significant portion of SEQ ID NO:1 and 2 are present in non-enterohaemorrhagic *E. coli* nucleic acid sequences and as such, hybridization conditions set forth in the claim does not define or particularly circumscribe those particular to enterohaemorrhagic *E. coli* or any particular serotype. There is no known or disclosed correlation of SEQ ID NO:1 or 2 variants and function particular to detection of particular enterohaemorrhagic *E. coli*. Therefore, it cannot be said that the disclosed function of detection of enterohaemorrhagic *E. coli* is sufficiently correlated to a particular, known structure recited by hybridization conditions. With respect to use of an assay (i.e. hybridization and detection) to support written description, the courts have held that disclosure of such screening assays having the desired activity, without disclosure of which polynucleotides have the desired characteristic, the claims failed to meet the written description requirement *University of Rochester v. G.D. Searle & Co.* 69 USPQ2D 1886 (CAFC 2004). Without any disclosure of what residues are required to function as claimed, the skilled artisan could not visualize or recognize the identity of the members of the genus that would be useful. The courts have held that when the specification discloses at most a specific DNA segment known to the inventor having a specific structure and biological characteristics, the disclosure is not commensurate in scope with the claims (*Ex parte Maizel*, 27 USPQ2d 1662). Applicants were not in possession of hybridizing derivatives of SEQ ID NO:1 or 2. The specification in particular teaches sequences pertaining to SEQ ID NO:1 were 100% homologous in all residues studied 272-264 of SEQ ID NO:1 (see specification page 6, first full paragraph). Thus, there are no disclosed hybridizing variants for the region set forth in claim 21. With respect to

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SEQ ID NO:2, there recitation of at least 14 consecutive nucleotides does not provide for a common core structure that correlates with function.

The rejection is maintained for reasons made of record.

Status of Claims

Claims 20 and 21 stand rejected. Claims 24 and 25 are objected to as depending from a rejected base claim. Claims 27-30 are allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner

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